

CHARLES F. PREUSS (State Bar No. 45783)
BRENDA N. BUONAIUTO (State Bar No. 173919)
DRINKER BIDDLE & REATH LLP
50 Fremont Street, 20th Floor
San Francisco, California 94105
Telephone: (415) 591-7500
Facsimile: (415) 591-7510
charles.preuss@dbi.com
brenda.buonaiuto@dbi.com

Attorneys for Defendants
ORTHO-MCNEIL PHARMACEUTICAL, INC., now
known as ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC.,
and MCKESSON CORPORATION

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

Case No.

**DEFENDANTS' ANSWER TO
COMPLAINT; DEMAND FOR JURY
TRIAL**

KATHLEEN ANDERSON, an individual;
MARY RUTH BAYGENTS, an individual;
LATOYA DUNLAP, an individual; JANE
ENGLAND, an individual; ANQUARLA
HADLEY, an individual; RHONDAGAIL
HOWARD, an individual; MELISSA
ISON, an individual; DOLORES
KICHART, an individual; JUNE
MCKENZIE, an individual; SHERKIA
MELLERSON, an individual; CHERI
THORNHILL, an individual; KATHRYN
TRUSLOW, an individual;

Plaintiffs,

v.

ORTHO-MCNEIL PHARMACEUTICAL,
INC., a Delaware Corporation;
MCKESSON CORP. and DOES 1-500,
inclusive,

Defendants.

Defendants Ortho-McNeil Pharmaceutical, Inc. ("OMP"), now known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMJPI"), and McKesson Corporation ("McKesson") (collectively "Defendants"), by and through counsel, hereby respond to the allegations set forth in Plaintiffs' Complaint (the "Complaint"), as follows:

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RICHARD W. WIERING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

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ANSWER TO INTRODUCTION

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3 1. Defendants are without knowledge or information sufficient to form a
4 belief as to Plaintiffs' allegations that they used ORTHO EVRA®. Defendants deny the
5 remaining allegations contained in paragraph 1 of Plaintiffs' Complaint.

6 2. Defendants admit that OMP, now known as OMJPI, manufactured,
7 advertised, promoted, marketed, sold and distributed ORTHO EVRA®. Defendants deny
8 the remaining allegations contained in paragraph 2 of Plaintiffs' Complaint.

9 3. Defendants admit that McKesson is a non-exclusive distributor of ORTHO
10 EVRA® and has its principal place of business in San Francisco, California. Defendants
11 deny the remaining allegations contained in paragraph 3 of Plaintiffs' Complaint.

12 4. Defendants admit that on the ORTHO EVRA® Web site, it stated that:
13 "The transdermal -- or 'through the skin' -- weekly birth control patch prevents
14 pregnancy by delivering continuous levels of the hormones norelgestromin and ethinyl
15 estradiol (progestin and estrogen, respectively) through the skin and into the
16 bloodstream." Defendants admit that the FDA approved the use of ORTHO EVRA® for
17 the prevention of pregnancy in November 2001. Defendants further admit that the FDA's
18 publications state what they state. Defendants deny the remaining allegations contained
19 in paragraph 4 of Plaintiffs' Complaint.

ANSWER TO JURISDICTION AND VENUE

20 5. Paragraph 5 of Plaintiffs' Complaint contains legal conclusions to which no
21 response is required.

22 6. Defendants admit that OMP, now known as OMJPI, was a Delaware
23 corporation with its principal place of business in New Jersey, that OMJPI is a
24 Pennsylvania corporation with its principal place of business in New Jersey, and that
25 McKesson is a Delaware corporation with its principal place of business in California.
26 Defendants deny the remaining allegations contained in paragraph 6 of Plaintiffs'
27 Complaint.

28 7. Defendants admit that McKesson has its principal place of business in San

1 Francisco, California. Defendants deny the remaining allegations contained in paragraph
2 7 of Plaintiffs' Complaint.

3 8. Defendants admit that McKesson has its principal place of business in San
4 Francisco, California. Defendants deny the remaining allegations contained in paragraph
5 8 of Plaintiffs' Complaint.

6 9. Defendants are without knowledge or information sufficient to form a
7 belief as to the allegations contained in paragraph 9 of Plaintiffs' Complaint.
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9 ANSWER TO PLAINTIFFS

10 10. Defendants are without knowledge or information sufficient to form a
11 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
12 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 10
13 of Plaintiffs' Complaint.

14 11. Defendants are without knowledge or information sufficient to form a
15 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
16 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 11
17 of Plaintiffs' Complaint.

18 12. Defendants are without knowledge or information sufficient to form a
19 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
20 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 12
21 of Plaintiffs' Complaint.

22 13. Defendants are without knowledge or information sufficient to form a
23 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
24 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 13
25 of Plaintiffs' Complaint.

26 14. Defendants are without knowledge or information sufficient to form a
27 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
28 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 14
of Plaintiffs' Complaint.

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15. Defendants are without knowledge or information sufficient to form a belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 15 of Plaintiffs' Complaint.

16. Defendants are without knowledge or information sufficient to form a belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 16 of Plaintiffs' Complaint.

17. Defendants are without knowledge or information sufficient to form a belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 17 of Plaintiffs' Complaint.

18. Defendants are without knowledge or information sufficient to form a belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 18 of Plaintiffs' Complaint.

19. Defendants are without knowledge or information sufficient to form a belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 19 of Plaintiffs' Complaint.

20. Defendants are without knowledge or information sufficient to form a belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 20 of Plaintiffs' Complaint.

21. Defendants are without knowledge or information sufficient to form a belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 21 of Plaintiffs' Complaint.

ANSWER TO DEFENDANTS

22. Defendants admit that OMP, now known as OMJPI, was a Delaware corporation with its principal place of business in New Jersey and that OMJPI is a Pennsylvania corporation with its principal place of business in New Jersey. Defendants deny the remaining allegations contained in paragraph 22 of Plaintiffs' Complaint.

23. Defendants admit that OMP, now known as OMJPI, conducts business in California. Defendants deny the remaining allegations contained in paragraph 23 of Plaintiffs' Complaint.

24. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 24 of Plaintiffs' Complaint, and therefore these allegations are denied.

25. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 25 of Plaintiffs' Complaint, and therefore these allegations are denied.

26. Defendants admit that OMP, now known as OMJPI, manufactured, marketed, promoted, sold and distributed ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 26 of Plaintiffs' Complaint.

27. Defendants admit that McKesson is a Delaware corporation with its principal place of business in San Francisco, California. Defendants further admit that McKesson conducts business in California. Defendants deny the remaining allegations contained in paragraph 27 of Plaintiffs' Complaint.

28. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 28 of Plaintiffs' Complaint, and therefore these allegations are denied.

29. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 29 of Plaintiffs' Complaint, and therefore these allegations are denied.

30. Defendants admit that McKesson is a non-exclusive distributor of ORTHO

1 EVRA®. Defendants deny the remaining allegations contained in paragraph 30 of
2 Plaintiffs' Complaint.

3 31. Defendants are without knowledge or information sufficient to form a
4 belief as to the allegations contained in paragraph 31 of Plaintiffs' Complaint.

5 32. Defendants are without knowledge or information sufficient to form a
6 belief as to the allegations contained in paragraph 32 of Plaintiffs' Complaint.

7 33. To the extent that paragraph 33 of Plaintiffs' Complaint alleges improper
8 conduct on the part of Defendants, such allegations are denied.

9 34. To the extent that paragraph 34 of Plaintiffs' Complaint alleges improper
10 conduct on the part of Defendants, such allegations are denied.

11 ANSWER TO GENERAL ALLEGATIONS

12 35. OMP, now known as OMJPI, admits that on the OMP Web site, it stated
13 that: "Ortho-McNeil Pharmaceutical is a pioneer in contraception and a leader in
14 women's health care. Ortho-McNeil offers the broadest range of prescription birth
15 control options..." OMP, now known as OMJPI, further admits that it manufactures and
16 sells ORTHO EVRA®, the first combination transdermal contraceptive patch.
17 Defendants deny the remaining allegations contained in paragraph 35 of Plaintiffs'
18 Complaint.

19 36. OMP, now known as OMJPI, admits that ORTHO EVRA® is the first and
20 only once-a-week birth control patch. OMP, now known as OMJPI, further admits that
21 on the ORTHO EVRA® Web site, it stated that: "The transdermal -- or 'through the skin'
22 -- weekly birth control patch prevents pregnancy by delivering continuous levels of the
23 hormones norelgestromin and ethinyl estradiol (progestin and estrogen, respectively)
24 through the skin and into the bloodstream." Defendants deny the remaining allegations
25 contained in paragraph 36 of Plaintiffs' Complaint.

26 37. Defendants admit that a New Drug Application ("NDA") was filed for
27 ORTHO EVRA®, denoted as 21-180, with the FDA in December 2000. Defendants
28 further admit that the FDA Medical Officer's Review for ORTHO EVRA® states what it

1 states. Defendants deny the remaining allegations contained in paragraph 37 of
2 Plaintiffs' Complaint.

3 38. Defendants admit that the FDA approved the use of ORTHO EVRA® for
4 the prevention of pregnancy in November 2001. Defendants deny the remaining
5 allegations contained in paragraph 38 of Plaintiffs' Complaint.

6 39. Defendants admit that as with all prescription medicine, adverse events are
7 reported to the FDA by a variety of people and entities. Defendants deny the remaining
8 allegations contained in paragraph 39 of Plaintiffs' Complaint.

9 40. Defendants admit that the FDA's publications state what they state.
10 Defendants deny the remaining allegations contained in paragraph 40 of Plaintiffs'
11 Complaint.

12 41. Defendants admit that the November 2005 package insert for ORTHO
13 EVRA® states what it states. To the extent that paragraph 41 of Plaintiffs' Complaint
14 alleges improper conduct on the part of Defendants, such allegations are denied.

15 42. OMP, now known as OMJPI, admits that ORTHO EVRA® is the first and
16 only once-a-week birth control patch. Defendants deny the remaining allegations
17 contained in paragraph 42 of Plaintiffs' Complaint.

18 43. Defendants deny the allegations contained in paragraph 43 of Plaintiffs'
19 Complaint.

20 44. Defendants admit that the package insert for ORTHO EVRA® states what
21 it states. To the extent that paragraph 44 of Plaintiffs' Complaint alleges improper
22 conduct on the part of Defendants, such allegations are denied.

23 45. Defendants deny the allegations contained in paragraph 45 of Plaintiffs'
24 Complaint.

25 46. Defendants state that they were subject only to those duties imposed by
26 applicable law, and deny the allegations contained in paragraph 46 of Plaintiffs'
27 Complaint to the extent they suggest any different or greater duties. Defendants further
28 deny that they failed to abide by any applicable legal duties.

1 47. Defendants deny the allegations contained in paragraph 47 of Plaintiffs'
2 Complaint.

3 48. Defendants deny the allegations contained in paragraph 48 of Plaintiffs'
4 Complaint.

5 49. Defendants deny the allegations contained in paragraph 49 of Plaintiffs'
6 Complaint.

7 50. Defendants deny the allegations contained in paragraph 50 of Plaintiffs'
8 Complaint.

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10 **ANSWER TO FRAUDULENT CONCEALMENT**

11 51. Defendants deny the allegations contained in paragraph 51 of Plaintiffs'
12 Complaint.

13 52. Defendants state that they were subject only to those duties imposed by
14 applicable law, and deny the allegations contained in paragraph 52 of Plaintiffs'
15 Complaint to the extent they suggest any different or greater duties. Defendants further
16 deny that they failed to abide by any applicable legal duties, and deny the remaining
17 allegations contained in this paragraph.

18 **ANSWER TO FIRST CAUSE OF ACTION**

19 **NEGLIGENCE**

20 53. Defendants repeat their answers to the allegations of paragraphs 1 through
21 52 of Plaintiffs' Complaint as if set forth at length herein.

22 54. Defendants state that they were subject only to those duties imposed by
23 applicable law, and deny the allegations contained in paragraph 54 of the First Cause of
24 Action of Plaintiffs' Complaint to the extent they suggest any different or greater duties.
25 Defendants further deny that they failed to abide by any applicable legal duties.

26 55. Defendants deny the allegations contained in paragraph 55 of the First
27 Cause of Action of Plaintiffs' Complaint.

28 56. Defendants deny the allegations contained in paragraph 56 of the First
Cause of Action of Plaintiffs' Complaint.

1 57. Defendants deny the allegations contained in paragraph 57 of the First
2 Cause of Action of Plaintiffs' Complaint.

3 58. Defendants deny the allegations contained in paragraph 58 of the First
4 Cause of Action of Plaintiffs' Complaint.

5 59. Defendants deny the allegations contained in paragraph 59 of the First
6 Cause of Action of Plaintiffs' Complaint.

7 60. Defendants deny the allegations contained in paragraph 60 of the First
8 Cause of Action of Plaintiffs' Complaint.

9 61. Defendants deny the allegation that ORTHO EVRA® is defective, and
10 deny the remaining allegations contained in paragraph 61 of the First Cause of Action of
11 Plaintiffs' Complaint.

12 62. Defendants deny the allegations contained in paragraph 62 of the First
13 Cause of Action of Plaintiffs' Complaint.

14 63. Defendants deny the allegations contained in paragraph 63 of the First
15 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in
16 the unnumbered paragraph following paragraph 63.

17 **ANSWER TO SECOND CAUSE OF ACTION**

18 **STRICT PRODUCT LIABILITY – FAILURE TO WARN**

19 64. Defendants repeat their answers to the allegations of paragraphs 1 through
20 63 of Plaintiffs' Complaint as if set forth at length herein.

21 65. Defendants admit that OMP, now known as OMJPI, manufactures and
22 supplies ORTHO EVRA®. Defendants deny the remaining allegations contained in
23 paragraph 65 of the Second Cause of Action of Plaintiffs' Complaint.

24 66. Defendants admit that OMP, now known as OMJPI, manufactures and
25 supplies ORTHO EVRA®. Defendants deny the remaining allegations contained in
26 paragraph 66 of the Second Cause of Action of Plaintiffs' Complaint.

27 67. Defendants deny the allegations contained in paragraph 67 of the Second
28 Cause of Action of Plaintiffs' Complaint.

1 68. Defendants deny the allegation that ORTHO EVRA® is defective, and
2 deny the remaining allegations contained in paragraph 68 of the Second Cause of Action
3 of Plaintiffs' Complaint.

4 69. Defendants deny the allegation that ORTHO EVRA® is defective, and
5 deny the remaining allegations contained in paragraph 69 of the Second Cause of Action
6 of Plaintiffs' Complaint.

7 70. Defendants deny the allegations contained in paragraph 70 of the Second
8 Cause of Action of Plaintiffs' Complaint.

9 71. Defendants deny the allegation that ORTHO EVRA® is defective, and
10 deny the remaining allegations contained in paragraph 71 of the Second Cause of Action
11 of Plaintiffs' Complaint.

12 72. Defendants deny the allegations contained in paragraph 72 of the Second
13 Cause of Action of Plaintiffs' Complaint.

14 73. Defendants deny the allegations contained in paragraph 73 of the Second
15 Cause of Action of Plaintiffs' Complaint.

16 74. Defendants deny the allegations contained in paragraph 74 of the Second
17 Cause of Action of Plaintiffs' Complaint.

18 75. Defendants deny the allegations contained in paragraph 75 of the Second
19 Cause of Action of Plaintiffs' Complaint.

20 76. Defendants deny the allegations contained in paragraph 76 of the Second
21 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in
22 the unnumbered paragraph following paragraph 76.

23 **ANSWER TO THIRD CAUSE OF ACTION**

24 **BREACH OF EXPRESS WARRANTY**

25 77. Defendants repeat their answers to the allegations of paragraphs 1 through
26 76 of Plaintiffs' Complaint as if set forth at length herein.

27 78. Defendants deny the allegations contained in paragraph 78 of the Third
28 Cause of Action of Plaintiffs' Complaint.

1 79. Defendants deny the allegations contained in paragraph 79 of the Third
2 Cause of Action of Plaintiffs' Complaint.

3 80. Defendants deny the allegations contained in paragraph 80 of the Third
4 Cause of Action of Plaintiffs' Complaint.

5 81. Defendants deny the allegations contained in paragraph 81 of the Third
6 Cause of Action of Plaintiffs' Complaint.

7 82. Defendants deny the allegations contained in paragraph 82 of the Third
8 Cause of Action of Plaintiffs' Complaint.

9 83. Defendants deny the allegations contained in paragraph 83 of the Third
10 Cause of Action of Plaintiffs' Complaint.

11 84. Defendants deny the allegations contained in paragraph 84 of the Third
12 Cause of Action of Plaintiffs' Complaint.

13 85. Defendants deny the allegations contained in paragraph 85 of the Third
14 Cause of Action of Plaintiffs' Complaint.

15 86. Defendants deny the allegations contained in paragraph 86 of the Third
16 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in
17 the unnumbered paragraph following paragraph 86.

18 **ANSWER TO FOURTH CAUSE OF ACTION**

19 **BREACH OF IMPLIED WARRANTY**

20 87. Defendants repeat their answers to the allegations of paragraphs 1 through
21 96 of Plaintiffs' Complaint as if set forth at length herein.

22 88. Defendants admit that OMP, now known as OMJPI, marketed, sold and
23 distributed ORTHO EVRA®, which is used for the prevention of pregnancy. Defendants
24 further admit that McKesson is a non-exclusive distributor of ORTHO EVRA®, and
25 deny that McKesson marketed or sold ORTHO EVRA®. The remainder of paragraph 88
26 of the Fourth Cause of Action of Plaintiffs' Complaint contains a legal conclusion to
27 which no response is required.

28 89. Paragraph 89 of the Fourth Cause of Action of Plaintiffs' Complaint

1 contains legal conclusions to which no response is required.

2 90. Defendants are without knowledge or information sufficient to form a
3 belief as to the allegations contained in paragraph 90 of the Fourth Cause of Action of
4 Plaintiffs' Complaint, and therefore these allegations are denied.

5 91. Defendants deny the allegations contained in paragraph 91 of the Fourth
6 Cause of Action of Plaintiffs' Complaint.

7 92. Defendants deny the allegations contained in paragraph 92 of the Fourth
8 Cause of Action of Plaintiffs' Complaint.

9 93. Defendants deny the allegations contained in paragraph 93 of the Fourth
10 Cause of Action of Plaintiffs' Complaint.

11 94. Defendants deny the allegations contained in paragraph 94 of the Fourth
12 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in
13 the unnumbered paragraph following paragraph 94.

14 **ANSWER TO FIFTH CAUSE OF ACTION**
15 **NEGLIGENT MISREPRESENTATION**

16 95. Defendants repeat their answers to the allegations of paragraphs 1 through
17 94 of Plaintiffs' Complaint as if set forth at length herein.

18 96. Defendants admit that OMP, now known as OMJPI, manufactures,
19 markets, promotes, and sells ORTHO EVRA®. Defendants further state that they were
20 subject only to those duties imposed by applicable law, and deny the allegations
21 contained in this paragraph to the extent they suggest any different or greater duties.
22 Defendants further deny that they failed to abide by any applicable legal duties, and deny
23 the remaining allegations contained in paragraph 96 of the Fifth Cause of Action of
24 Plaintiffs' Complaint.

25 97. Defendants deny the allegations contained in paragraph 97 of the Fifth
26 Cause of Action of Plaintiffs' Complaint.

27 98. Defendants deny the allegations contained in paragraph 98 of the Fifth
28 Cause of Action of Plaintiffs' Complaint.

1 99. Defendants deny the allegations contained in paragraph 99 of the Fifth
2 Cause of Action of Plaintiffs' Complaint.

3 100. Defendants deny the allegations contained in paragraph 100 of the Fifth
4 Cause of Action of Plaintiffs' Complaint.

5 101. Defendants deny the allegations contained in paragraph 101 of the Fifth
6 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in
7 the unnumbered paragraph following paragraph 101.

8 **ANSWER TO SIXTH CAUSE OF ACTION**

9 **FRAUD**

10 102. Defendants repeat their answers to the allegations of paragraphs 1 through
11 101 of Plaintiffs' Complaint as if set forth at length herein.

12 103. Defendants admit that OMP, now known as OMJPI, manufactures,
13 markets, promotes, and sells ORTHO EVRA®. Defendants further state that they were
14 subject only to those duties imposed by applicable law, and deny the allegations
15 contained in this paragraph to the extent they suggest any different or greater duties.
16 Defendants further deny that they failed to abide by any applicable legal duties, and deny
17 the remaining allegations contained in paragraph 103 of the Sixth Cause of Action of
18 Plaintiffs' Complaint.

19 104. Defendants deny the allegations contained in paragraph 104 of the Sixth
20 Cause of Action of Plaintiffs' Complaint.

21 105. Defendants deny the allegations contained in paragraph 105 of the Sixth
22 Cause of Action of Plaintiffs' Complaint.

23 106. Defendants deny the allegations contained in paragraph 106 of the Sixth
24 Cause of Action of Plaintiffs' Complaint.

25 107. Defendants deny the allegations contained in paragraph 107 of the Sixth
26 Cause of Action of Plaintiffs' Complaint.

27 108. Defendants deny the allegations contained in paragraph 108 of the Sixth
28 Cause of Action of Plaintiffs' Complaint.

109. Defendants deny the allegations contained in paragraph 109 of the Sixth Cause of Action of Plaintiffs' Complaint.

110. Defendants deny the allegations contained in paragraph 110 of the Sixth Cause of Action of Plaintiffs' Complaint.

111. Defendants are without knowledge or information sufficient to form a belief as to Plaintiffs' states of mind. Defendants deny the remaining allegations contained in paragraph 111 of the Sixth Cause of Action of Plaintiffs' Complaint.

112. Defendants deny the allegations contained in paragraph 112 of the Sixth Cause of Action of Plaintiffs' Complaint.

113. Defendants deny the allegations contained in paragraph 113 of the Sixth Cause of Action of Plaintiffs' Complaint.

114. Defendants deny the allegations contained in paragraph 114 of the Sixth Cause of Action of Plaintiffs' Complaint.

115. Defendants deny the allegations contained in paragraph 115 of the Sixth Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in the unnumbered paragraph following paragraph 115.

FIRST AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state a claim against Defendants upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

Venue is improper in this court.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs are fraudulently joined and/or misjoined, and the court should sever Plaintiffs' claims and/or enter other appropriate orders to avoid prejudice, unfairness, hardship, delay, and undue expense and to promote convenience and expedience.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent certain Plaintiffs

1 have asserted duplicative claims in one or more other actions pending against some or all
2 of the same defendants.

3
4 **FIFTH AFFIRMATIVE DEFENSE**

5 Plaintiffs' claims are barred by the applicable statute of limitations, statute of
6 repose and/or by the equitable doctrines of laches and estoppel.

7 **SIXTH AFFIRMATIVE DEFENSE**

8 Plaintiffs' claims are barred by the doctrines of informed consent, release and
9 waiver.

10 **SEVENTH AFFIRMATIVE DEFENSE**

11 Plaintiffs' claims are barred because the alleged damages, if any are proven, were
12 not proximately caused by any act or omission of any of the Defendants.

13 **EIGHTH AFFIRMATIVE DEFENSE**

14 If Plaintiffs suffered any of the injuries, losses and damages alleged, then said
15 injuries, losses and damages were a direct and proximate result of a responsible,
16 superseding, and/or intervening cause.

17 **NINTH AFFIRMATIVE DEFENSE**

18 Defendants state that if Plaintiffs have suffered any of the injuries, losses and
19 damages alleged, then said injuries, losses and damages were due to an allergic,
20 idiosyncratic or idiopathic reaction to the product at issue in this case, or by an
21 unforeseeable illness, unavoidable accident or preexisting condition, without any
22 negligence and culpable conduct by Defendants.

23 **TENTH AFFIRMATIVE DEFENSE**

24 Plaintiffs' injuries and damages, if any, were caused in whole or in part by the acts
25 (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration,
26 omission or fault of one or more persons or entities over whom Defendants exercised no
27 control and for whom Defendants are not legally responsible, including, without
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1 limitation, Plaintiffs.

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3 **ELEVENTH AFFIRMATIVE DEFENSE**

4 Plaintiffs failed to exercise reasonable care and diligence to mitigate injuries and
5 damages, if any.

6 **TWELFTH AFFIRMATIVE DEFENSE**

7 Plaintiffs' claims are barred by the "state of the art" and "state of scientific
8 knowledge" defenses.

9 **THIRTEENTH AFFIRMATIVE DEFENSE**

10 Plaintiffs' claims are barred by the Learned Intermediary Doctrine.

11 **FOURTEENTH AFFIRMATIVE DEFENSE**

12 The product at issue in this case falls under the auspices of the Food, Drug and
13 Cosmetic Act and regulations promulgated by the Federal Food & Drug Administration,
14 and therefore, Federal law preempts Plaintiffs' claims. *See*, 21 U.S.C. §301 *et. seq.* *See*
15 *also*, 71 Fed. Reg. 3922 (January 24, 2006).

16 **FIFTEENTH AFFIRMATIVE DEFENSE**

17 Defendants did not make to Plaintiffs nor did they breach any express or implied
18 warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely
19 on any theory of breach of warranty, such claims are barred by applicable law, and for
20 lack of privity with Defendants and/or for failure of Plaintiffs, or Plaintiffs'
21 representatives, to give timely notice to Defendants of any alleged breach of warranty.
22 Plaintiffs did not rely on any alleged warranty. Defendants further specifically plead as
23 to any breach of warranty claim all affirmative defenses under the Uniform Commercial
24 Code existing and which may arise in the future, as enacted in the State of California, and
25 any other state whose law is deemed to apply in this case.

26 **SIXTEENTH AFFIRMATIVE DEFENSE**

27 Plaintiffs' claims are barred by comments j and k to Section 402A of the
28

1 Restatement (Second) of Torts.

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3 **SEVENTEENTH AFFIRMATIVE DEFENSE**

4 Plaintiffs' claims of product defects are barred by Section 2, 4, and 6(c) and (d) of
5 the Restatement (Third) of Torts: Products Liability.

6 **EIGHTEENTH AFFIRMATIVE DEFENSE**

7 Plaintiffs' product liability claims are barred because the benefits of the relevant
8 product outweighed its risks.

9 **NINETEENTH AFFIRMATIVE DEFENSE**

10 Plaintiffs' claims are barred in whole or part because the product at issue was at all
11 times properly prepared, packaged, and distributed, and was not defective or
12 unreasonably dangerous.

13 **TWENTIETH AFFIRMATIVE DEFENSE**

14 Any imposition of punitive damages in this case against Defendants is barred to
15 the extent that the manner in which such punitive damages are calculated violates the
16 Constitution of the United States or the Constitution of the State of California.

17 **TWENTY-FIRST AFFIRMATIVE DEFENSE**

18 Any award of punitive damages in this case against Defendants is barred to the
19 extent that the amount of such an award violates the Constitution of the United States or
20 the Constitution of the State of California.

21 **TWENTY-SECOND AFFIRMATIVE DEFENSE**

22 Plaintiffs have failed to plead fraud with specificity.

23 **TWENTY-THIRD AFFIRMATIVE DEFENSE**

24 Defendants are entitled to a setoff for all amounts paid, payable by or available
25 from collateral sources.
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TWENTY-FOURTH AFFIRMATIVE DEFENSE

The Complaint fails to state a cause of action against Defendants because there is no private right of action under the applicable federal law. To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to FDA, such claims are barred pursuant to *Buckman v. Plaintiffs' Legal Community*, 531 U.S. 341 (2001).

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the product at issue, barring in whole or in part the damages Plaintiffs seek to recover.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

In the event Defendants, or any of them, are held liable to Plaintiffs, or any of them, which liability is expressly denied, or a settlement of judgment against Defendants, or any of them, is reached, Defendants request an apportionment of fault be made as permitted by *Li v. Yellow Cab Company*, 13 Cal.3d 804 (1975) and *American Motorcycle Association v. Superior Court*, 20 Cal.3d 578 (1987) and a judgment and declaration of indemnification and contribution be entered against all other persons and entities in accordance with that apportionment of fault.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

The amount of any award on behalf of Plaintiffs, or any of them, for non-economic loss must be allocated according to the provisions of California Civil Code Section 1431.2 ("Proposition 51").

TWENTY- EIGHTH AFFIRMATIVE DEFENSE

Defendants specifically reserve the right to amend their Answer by adding defenses, counterclaims, cross claims or by instituting third party actions as additional facts are obtained.

1 WHEREFORE, having fully answered, Defendants specifically controvert
2 Plaintiffs' Prayer for Relief including Paragraphs (1)-(6).
3

4 **JURY DEMAND**

5 Defendants hereby demand a trial by jury of all the facts and issues in this case
6 pursuant to Federal Rule of Civil Procedure 38(b).
7

8 Dated: February 7, 2008

DRINKER BIDDLE & REATH

9 

10 CHARLES F. PREUSS

BRENDA N. BUONAIUTO

11 Attorneys for Defendants

12 ORTHO-MCNEIL PHARMACEUTICAL,

13 INC., now known as ORTHO-MCNEIL-

14 JANSSEN PHARMACEUTICALS, INC.,

15 and MCKESSON CORPORATION
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